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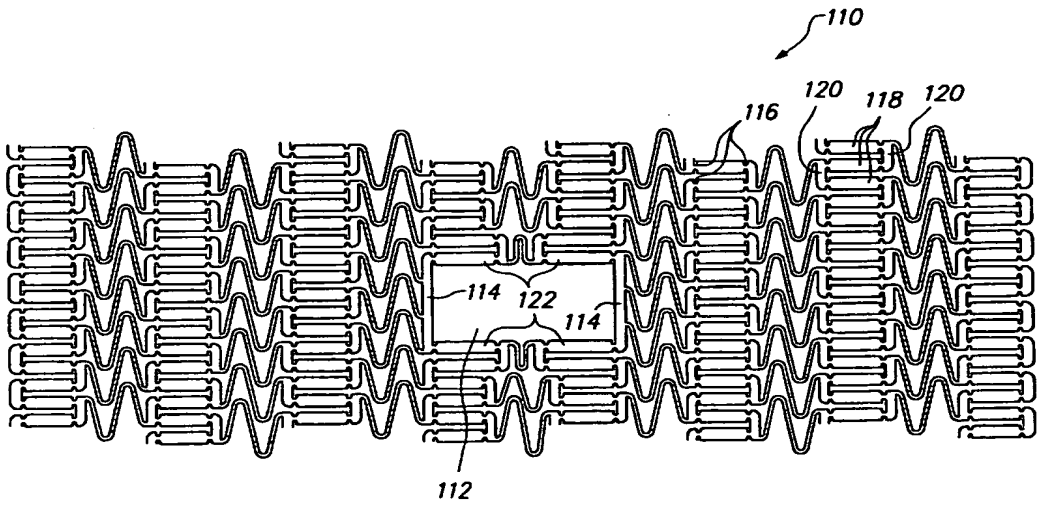
(54) Title: EXPANDABLE MEDICAL STENT WITH DUCTILE HINGES



(57) Abstract: An expandable tissue supporting device of the present invention employs ductile hinges at selected points in the expandable device. When expansion forces are applied to the device as a whole, the ductile hinges concentrate expansion stresses and strains in small well defined areas. The expandable tissue supporting device includes a plurality of elongated beams arranged in a cylindrical device and connected together by a plurality of ductile hinges. Although many ductile hinge configurations are possible, the ductile hinges preferably have a substantially constant hinge cross sectional area which is smaller than a beam cross sectional area such that as the device is expanded from a first diameter to a second diameter, the ductile hinges experience plastic deformation while the beams are not plastically deformed. The expandable tissue supporting device can be provided with segments which may be expanded in a specified sequence and/or framed hole features for accommodating bifurcations.

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U.S. Pat. Nos. 4,733,665, 4,739,762, and 4,776,337 disclose expandable and deformable interluminal vascular grafts in the form of thin-walled tubular members with axial slots allowing the members to be expanded radially outwardly into contact with a body passageway. After insertion, the tubular members are mechanically expanded beyond their elastic limit and thus permanently fixed within the body. The force required to expand these tubular stents is proportional to the thickness of the wall material in a radial direction. To keep expansion forces within acceptable levels for use within the body (e.g., 5 - 10 atm), these designs must use very thin-walled materials (e.g., stainless steel tubing with 0.0025 inch thick walls). However, materials this thin are not visible on conventional fluoroscopic and x-ray equipment and it is therefore difficult to place the stents accurately or to find and retrieve stents that subsequently become dislodged and lost in the circulatory system.

Further, many of these thin-walled tubular stent designs employ networks of long, slender struts whose width in a circumferential direction is two or more times greater than their thickness in a radial direction. When expanded, these struts are frequently unstable, that is, they display a tendency to buckle, with individual struts twisting out of plane. Excessive protrusion of these twisted struts into the bloodstream has been observed to increase turbulence, and thus encourage thrombosis. Additional procedures have often been required to attempt to correct this problem of buckled struts. For example, after initial stent implantation is determined to have caused buckling of struts, a second, high-pressure balloon (e.g., 12 to 18 atm) would be used to attempt to drive the twisted struts further into the lumen wall. These secondary procedures can be dangerous to the patient due to the risk of collateral damage to the lumen wall.

Many of the known stents display a large elastic recovery, known in the field as "recoil," after expansion inside a lumen. Large recoil necessitates over-expansion of the stent during implantation to achieve the desired final diameter. Over-expansion is

also more expensive, and more difficult to fabricate and machine than other stent materials, such as stainless steel.

All of the above stents share a critical design property: in each design, the features that undergo permanent deformation during stent expansion are prismatic, i.e., the cross sections of these features remain constant or change very gradually along their entire active length. To a first approximation, such features deform under transverse stress as simple beams with fixed or guided ends: essentially, the features act as a leaf springs. These leaf spring like structures are ideally suited to providing large amounts of elastic deformation before permanent deformation commences. This is exactly the opposite of ideal stent behavior. Further, the force required to deflect prismatic stent struts in the circumferential direction during stent expansion is proportional to the square of the width of the strut in the circumferential direction. Expansion forces thus increase rapidly with strut width in the above stent designs. Typical expansion pressures required to expand known stents are between about 5 and 10 atmospheres. These forces can cause substantial damage to tissue if misapplied.

FIG. 1 shows a typical prior art "expanding cage" stent design. The stent 10 includes a series of axial slots 12 formed in a cylindrical tube 14. Each axial row of slots 12 is displaced axially from the adjacent row by approximately half the slot length providing a staggered slot arrangement. The material between the slots 12 forms a network of axial struts 16 joined by short circumferential links 18. The cross section of each strut 16 remains constant or varies gradually along the entire length of the strut and thus the rectangular moment of inertia and the elastic and plastic section moduli of the cross section also remain constant or vary gradually along the length of the strut. Such a strut 16 is commonly referred to as a prismatic beam. Struts 16 in this type of design are typically 0.005 to 0.006 inches (0.127 - 0.1524 mm) wide in the circumferential direction. Strut thicknesses in the radial direction are typically about 0.0025 inches (0.0635 mm) or less to keep expansion forces within acceptable levels. However, most stent materials must be approximately 0.005 inches (0.127 mm) thick

In addition, it would be advantageous to have a tissue-supporting device with minimal elastic recovery, or "recoil" of the device after expansion.

It would be advantageous to have a tissue supporting device that can be securely crimped to the delivery catheter without requiring special tools, techniques, or ancillary clamping features.

It would further be advantageous to have a tissue-supporting device that has improved resistance to compressive forces (improved crush strength) after expansion.

It would also be advantageous to have a tissue-supporting device that achieves all the above improvements with minimal foreshortening of the overall stent length during expansion.

Finally, it would also be advantageous to provide a tissue-supporting device which is differentially expandable and/or which has framed hole features for accommodating bifurcations.

SUMMARY OF THE INVENTION

The present invention addresses several important problems in expandable medical device design including: high expansion force requirements; lack of radio-opacity in thin-walled stents; buckling and twisting of stent features during expansion; poor crimping properties; and excessive elastic recovery ("recoil") after implantation. The invention also provides benefits of improved resistance to compressive forces after expansion, control of the level of plastic strain, and low axial shortening during expansion. Some embodiments of the invention also provide improved uniformity of expansion by limiting a maximum geometric deflection between struts. Other embodiments of the invention include segments of the expandable device which may be expanded in a specified sequence and/or framed hole features for accommodating bifurcations.

In accordance with another aspect of the present invention, a method of expanding a medical device includes the steps of:

providing a substantially cylindrical expandable medical device having a first section with ductile hinges of a first configuration and a second section with ductile hinges of a second configuration which requires a different force for expansion than the first configuration; and

expanding the device in a controlled expansion sequence with an expandable member.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

FIG. 1 is an isometric view of a prior art tissue-supporting device;

FIG. 2 is an isometric view of a tissue-supporting device in accordance with one embodiment of the invention;

FIGS. 3a-d are perspective views of ductile hinges according to several variations of the invention;

FIG. 3e is a side view of another embodiment of a ductile hinge;

FIGS. 4a and 4b are an isometric view and an enlarged side view of a tissue-supporting device in accordance with an alternative embodiment of the invention;

FIGS. 5a-5c are perspective, side, and cross-sectional views of an idealized ductile hinge for purposes of analysis;

FIG. 5d is a stress/strain curve for the idealized ductile hinge;

FIGS. 6 is a perspective view of a simple beam for purposes of calculation;

FIG. 7 is a moment verses curvature graph for a rectangular beam;

FIG. 8 is an enlarged side view of a bent ductile hinge;

features. The reduced sections 32 of the struts function as hinges in the cylindrical structure. Since the stress/strain concentration features 32 are designed to operate into the plastic deformation range of generally ductile materials, they are referred to as ductile hinges. Such features are also commonly referred to as "Notch Hinges" or "Notch Springs" in ultra-precision mechanism design, where they are used exclusively in the elastic range.

With reference to the drawings and the discussion, the *width* of any feature is defined as its dimension in the circumferential direction of the cylinder. The *length* of any feature is defined as its dimension in the axial direction of the cylinder. The *thickness* of any feature is defined as the wall thickness of the cylinder.

The presence of the ductile hinges 32 allows all of the remaining features in the tissue supporting device to be increased in width or the circumferentially oriented component of their respective rectangular moments of inertia - thus greatly increasing the strength and rigidity of these features. The net result is that elastic, and then plastic deformation commence and propagate in the ductile hinges 32 before other structural elements of the device undergo any significant elastic deformation. The force required to expand the tissue supporting device 20 becomes a function of the geometry of the ductile hinges 32, rather than the device structure as a whole, and arbitrarily small expansion forces can be specified by changing hinge geometry for virtually any material wall thickness. In particular, wall thicknesses great enough to be visible on a fluoroscope can be chosen for any material of interest.

In order to get minimum recoil, the ductile hinges 32 should be designed to operate well into the plastic range of the material, and relatively high local strain-curvatures are developed. When these conditions apply, elastic curvature is a very small fraction of plastic or total curvature, and thus when expansion forces are relaxed, the percent change in hinge curvature is very small. When incorporated into a strut network designed to take maximum advantage of this effect, the elastic springback, or "recoil," of the overall stent structure is minimized.

laser beams often used to fabricate these features are themselves round, slots or notches with circular roots are also among the easiest to fabricate.

FIG. 3a shows a ductile hinge 36 formed by a pair of opposed circular grooves 38, 40. According to this embodiment the circumferential slot 26 has semicircular ends 38 having a radius of curvature r. Outer semicircular grooves 40 opposed the semicircular ends 38 and also have a radius of curvature r. FIG. 3c shows another ductile hinge 54 formed by a parabolic groove 56.

Generally, the ductile hinges 36 of the embodiment of FIG. 3a formed between pairs of concave curves 38, 40 have a minimum width along a line connecting their respective centers of curvature. When the struts connected by the ductile hinge are moved apart or together, plastic deformation is highly concentrated in a region immediately adjacent to the plane that bisects the hinge at this narrow point.

For smaller deflection, this very high strain concentration at the bisecting plane is acceptable, and in some cases, useful. For stent crimping purposed, for example, it is desirable to generate relatively large plastic deformations at very small deflection angles.

As a practical matter, however, strut deflection angles for device *expansion* are often in the 25° to 45° range. At these angles, strain at the root or bisecting plane of concave ductile hinge features can easily exceed the 50 to 60% elongation-to-failure of 316L stainless steel, one of the most ductile stent materials. Deflection limiting features which will be described further below limit the *geometric* deflection of struts, but these features do not in themselves affect the propagation pattern of plastic deformation in a given ductile hinge design. For concave ductile hinges at large bend angles, very high strain concentrations remain. Scanning electron micrographs have confirmed this analysis.

In many engineering applications, it is desirable to limit the amount of strain, or "cold-work," in a material to a specified level in order to optimize material properties and to assure safe operation. For example, in medical applications it is desirable to

FIG. 3e shows an asymmetric ductile hinge 63 that produces different strain versus deflection-angle functions in expansion and compression. Each of the ductile hinges 64 is formed between a convex surface 68 and a concave surface 69. The ductile hinge 64 according to a preferred embodiment essentially takes the form of a small, prismatic curved beam having a substantially constant cross section. However, a thickness of the curved ductile hinge 64 may vary somewhat as long as the ductile hinge width remains constant along a portion of the hinge length. The width of the curved beam is measured along the radius of curvature of the beam. This small curved beam is oriented such that the smaller *concave* surface 69 is placed in tension in the device *crimping* direction, while the larger *convex* surface 68 of the ductile hinges is placed in tension in the device *expansion* direction. Again, there is no local minimum width of the ductile hinge 64 along the (curved) ductile hinge axis, and no concentration of material strain. During device expansion tensile strain will be distributed along the convex surface 68 of the hinge 64 and maximum expansion will be limited by the angle of the walls of the concave notch 69 which provide a geometric deflection limiting feature. Maximum tensile strain can therefore be reliably limited by adjusting the initial length of the convex arc shaped ductile hinge 64 over which the total elongation is distributed.

The ductile hinges illustrated in FIGS. 3a-e are examples of different structures that will function as a stress/strain concentrator. Many other stress/strain concentrator configurations may also be used as the ductile hinges in the present invention. The ductile hinges according to the present invention generally include an abrupt change in width of a strut that functions to concentrate stresses and strains in the narrower section of the strut. These ductile hinges also generally include features to limit mechanical deflection of attached struts and features to control material strain during large strut deflections. Although the ductile hinges have been illustrated in FIG. 2 as positioned at the ends of each of the axial slots 22, they may also be positioned at other locations in other designs without departing from the present invention.

for making the tissue supporting device 20, 80 involves forming a cylindrical tube and then laser cutting the slots 22, 26, 86, 92 and notches 94 into the tube. Alternatively, the tissue supporting device may be formed by electromachining, chemical etching followed by rolling and welding, or any other known method.

The design and analysis of stress/strain concentration for ductile hinges, and stress/strain concentration features in general, is complex. For example, the stress concentration factor for the simplified ductile hinge geometry of FIG. 3a can be calculated and is given by the following expression where D is the width of the struts 28, h is the height of the circular grooves 38, 40, and r is the radius of curvature of the grooves. For purposes of this example the ratio of h/r is taken to be 4. However, other ratios of h/r can also be implemented successfully.

$$K = 4.935 - 7.586\left(\frac{2h}{D}\right) + 0.515\left(\frac{2h}{D}\right)^2 + 0.432\left(\frac{2h}{D}\right)^3$$

The stress concentration factors are generally useful only in the linear elastic range. Stress concentration patterns for a number of other geometries can be determined through photoelastic measurements and other experimental methods. Stent designs based on the use of stress/strain concentration features, or ductile hinges, generally involve more complex hinge geometries and operate in the non-linear elastic and plastic deformation regimes.

The general nature of the relationship among applied forces, material properties, and ductile hinge geometry can be more easily understood through analysis of an idealized hinge 66 as shown in FIGS. 5a-5c. The hinge 66 is a simple beam of rectangular cross section having a width h, length L and thickness b. The idealized hinge 66 has elastic-ideally-plastic material properties which are characterized by the

inflation of a balloon or by a mandrel. The tissue supporting device 20 in the expanded condition has a diameter which is preferably up to three times the diameter of the device in the initial unexpanded condition.

Many tissue supporting devices fashioned from cylindrical tubes comprise networks of long, narrow, prismatic beams of essentially rectangular cross section as shown in FIG. 6. These beams which make up the known tissue supporting devices may be straight or curved, depending on the particular design. Known expandable tissue supporting devices have a typical wall thickness b of 0.0025 inches (0.0635 mm), and a typical strut width h of 0.005 to 0.006 inches (0.127 - 0.1524 mm). The ratio of b:h for most known designs is 1:2 or lower. As b decreases and as the beam length L increases, the beam is increasingly likely to respond to an applied bending moment M by buckling, and many designs of the prior art have displayed this behavior. This can be seen in the following expression for the "critical buckling moment" for the beam of FIG. 6.

$$M_{crit} = \frac{\pi b^3 h \sqrt{EG(1-0.63\ b/h)}}{6L}$$

Where: E = Modulus of Elasticity

G = Shear Modulus

By contrast, in a ductile hinge based design according to the present invention, only the hinge itself deforms during expansion. The typical ductile hinge 32 is not a long narrow beam as are the struts in the known stents. Wall thickness of the present invention may be increased to 0.005 inches (0.127 mm) or greater, while hinge width is typically 0.002 - 0.003 inches (0.0508 - 0.0762 mm), preferably 0.0025 inches (0.0635 mm) or less. Typical hinge length, at 0.002 to 0.005 inches (0.0508 - 0.0127 mm), is more than an order of magnitude less than typical strut length. Thus, the ratio of b:h in a typical ductile hinge 32 is 2:1 or greater. This is an inherently stable ratio, meaning that the plastic moment for such a ductile hinge beam is much lower than the critical

$$M_p = \frac{3}{2} M_{yp} \Rightarrow \kappa_{rebound} = \frac{3}{2} \kappa_{yp}$$

Imparting additional curvature in the plastic zone cannot further increase the elastic curvature, but *will* decrease the ratio of elastic to plastic curvature. Thus, additional curvature or larger expansion of the tissue supporting device will reduce the percentage recoil of the overall stent structure.

As shown in FIG. 8, when a rigid strut 28 is linked to the ductile hinge 66 described above, the strut 28 forms an angle θ with the horizontal that is a function of hinge curvature. A change in hinge curvature results in a corresponding change in this angle θ. The angular elastic rebound of the hinge is the change in angle $\Delta\ \theta$ that results from the rebound in elastic curvature described above, and thus angular rebound also approaches a limiting value as plastic deformation proceeds. The following expression gives the limiting value of angular elastic rebound for the idealized hinge of FIG. 8.

$$\theta_{rebound} = 3\epsilon_{yp} \frac{L}{h}$$

Where strain at the yield point is an independent material property (yield stress divided by elastic modulus); L is the length of the ductile hinge; and h is the width of the hinge. For non-idealized ductile hinges made of real materials, the constant 3 in the above expression is replaced by a slowly rising function of total strain, but the effect of geometry would remain the same. Specifically, the elastic rebound angle of a ductile hinge decreases as the hinge width h increases, and increases as the hinge length L increases. To minimize recoil, therefore, hinge width h should be increased and length L should be decreased.

Ductile hinge width h will generally be determined by expansion force criteria, so it is important to reduce hinge length to a practical minimum in order to minimize

According to one example of the tissue supporting device of the invention, the device can be expanded by application of an internal pressure of about 2 atmospheres or less, and once expanded to a diameter between 2 and 3 times the initial diameter can withstand a compressive force of about 16 to 20 gm/mm or greater. Examples of typical compression force values for prior art devices are 3.8 to 4.0 gm/mm.

While both recoil and crush strength properties of tissue supporting devices can be improved by use of ductile hinges with large curvatures in the expanded configuration, care must be taken not to exceed an acceptable maximum strain level for the material being used. For the ductile hinge 44 of FIG. 3b, for example, it may be shown that the maximum material strain for a given bend angle is given by the expression:

$$\epsilon_{max} = \frac{h}{L}\,\frac{\theta}{2}$$

Where ϵ_{max} is maximum strain, h is ductile hinge width, L is ductile hinge length and θ is bend angle in radians. When strain, hinge width and bend angle are determined through other criteria, this expression can be evaluated to determine the correct ductile hinge length L.

For example, suppose the ductile hinge 44 of FIG. 3b was to be fabricated of 316L stainless steel with a maximum strain of 30%; ductile hinge width h is set at 0.0025 inch (0.0635 mm) by expansion force criteria; and the bend angle θ is mechanically limited to 0.5 radians ($\cong$ 30%) at full stent expansion. Solving the above expression for L gives the required ductile hinge length of at least about 0.0033 inches (0.0838 mm).

Similar expressions may be developed to determine required lengths for more complicated ductile hinge geometries, such as shown in FIG. 3e. Typical values for the

This ability to control axial contraction based on hinge and strut design provides great design flexibility when using ductile hinges. For example, a stent could be designed with zero axial contraction.

An alternative embodiment that illustrates the trade off between crush strength and axial contraction is shown in FIG. 10. FIG. 10 shows a portion of a tissue supporting device 70 having an array of struts 72 and ductile hinges 74 in the unexpanded state. The struts 72 are positioned initially at an angle θ_1 with respect to a longitudinal axis X of the device. As the device is expanded radially from the unexpanded state illustrated in FIG. 10, the angle θ_1 increases. In this case the device contracts axially from the onset of vertical expansion throughout the expansion. Once the device has been completely expanded the final angle θ_1 made by the strut 72 with the horizontal will be much greater than the angle θ in the device of FIG. 8a and 8b. As shown previously, a higher final strut angle θ_1, can significantly increase crush strength and decrease circumferential recoil of the stent structure. However, there is a trade off between increased crush strength and increase in axial contraction.

According to one example of the present invention, the struts 72 are positioned initially at an angle of about 0° to 45° with respect to a longitudinal axis of the device. As the device is expanded radially from the unexpanded state illustrated in FIG. 10a, the strut angle increases to about 20° to 80°.

Tissue supporting devices including ductile hinges as described above can be used to create many useful device configurations in addition to the substantially cylindrical devices described above. For example, tissue supporting devices having ductile hinges may be designed in which various sections or areas of the device open at differential expansion pressures by varying the hinge configuration. This feature makes it possible to control the expansion sequence of different features and areas of the device. Another tissue supporting device design variation allows the creation of specially shaped side-access holes in the device which open up as the device expands and can be used accommodate vessel bifurcations.

cylindrical sections, longitudinal sections, rectangular sections, or sections of any other shape. Differential expansion is very useful in special deployment situations, such as treatment of bifurcations, and in creating special tissue supporting device features, such as side access holes as shown in FIGS. 12a-12c.

A framed hole feature, such as the feature shown in FIGS. 12a-12c, is capable of providing strong, uniform support to the tissue at a bifurcation in an artery. Known techniques for treating bifurcations generally deliver a mesh tissue supporting device into the artery and position the device over the bifurcation. According to the known methods, a surgeon then attempts to create one or more branch lumen access holes by inserting a balloon through the sidewall of the mesh device, and then inflating the balloon to simply push the local features of the mesh aside. These techniques are inherently random in nature: the exact point of expansion in the device lattice cannot be predicted, and the device may or may not expand satisfactorily at that point. Tissue support provided by these known techniques for treating bifurcated arteries is similarly unpredictable.

FIG. 12a shows an unexpanded tissue support device 110 in which a rectangular hole 112 has been formed in the center. Ductile hinges 116 connect all the struts 118 and links 120 of the device as described above with respect to the previous embodiments. The ends of the device 110 have a regular pattern of struts 118 and ductile hinges 116. The hole 112 is formed by removing several axial struts and connecting their respective side links into two longer circumferential side links 114, which provide a vertical frame for the hole 112. The struts 122 which frame the hole 112 and connect the side links 114 may be straight, as shown, rounded, or contoured in some other way, depending on the desired final shape of the expanded hole feature.

According to one alternative embodiment of the invention, the ductile hinges 116 connecting the frame struts 122 and the side links 114 will be designed to open at a somewhat lower inflation pressure than the remainder of the ductile hinges around the rest of the circumference of the device. Thus, when the device 110 is expanded the

coatings on the struts, such as polymer coatings containing beneficial agents, laser drilled holes in the struts containing beneficial agent, and the like.

While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention.

5. The expandable medical device according the Claim 1, further comprising a geometric deflection limiting feature for limiting an amount of bending of the ductile hinges.

6. The expandable medical device according to Claim 5, wherein the geometric deflection limiting feature is a V-shaped notch having side surfaces which contact each other when a maximum amount of bending is reached.

7. The expandable medical device according to Claim 1, wherein the plurality of elongated beams extend substantially axially and a plurality of circumferential beams are each connected at first and second ends to one of the axial beams by a ductile hinge.

8. The expandable medical device according to Claim 1, further comprising a side access hole formed in the device in an unexpanded state which accommodate a vessel bifurcation when the device is expanded.

9. An expandable medical device comprising:

a plurality of elongated beams, the plurality of elongated beams joined together in a regular pattern to form a substantially cylindrical device which is radially expandable, the plurality of elongated beams having a beam width in a circumferential direction;

a plurality of ductile hinges connecting the plurality of beams together in the substantially cylindrical device, the ductile hinges having a width in a circumferential direction along a portion of a hinge length which is smaller than the

15. A method of expanding a medical device comprising:

providing a substantially cylindrical expandable medical device having a first section with ductile hinges of a first configuration and a second section with ductile hinges of a second configuration which requires a different force for expansion than the first configuration; and

expanding the device in a controlled expansion sequence with an expandable member.

16. The method according to Claim 15, wherein the hinges having the first configuration have a first hinge width which is smaller than a second hinge width of the hinges having the second configuration.

17. The method according to Claim 15, wherein the first section is expanded prior to expansion of the second section.

18. The method according to Claim 15, wherein the expansion is performed by inflating a balloon inside the cylindrical device.

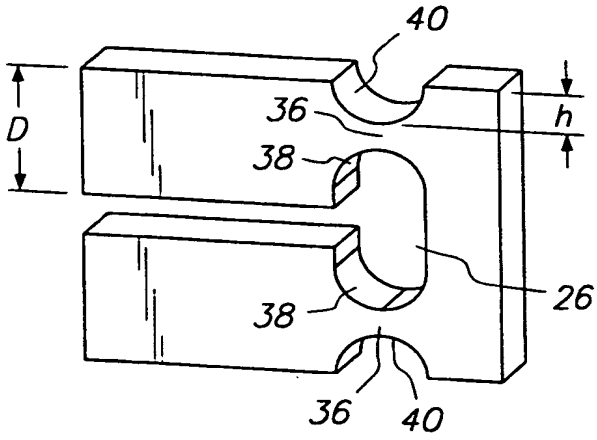

FIG. 3a

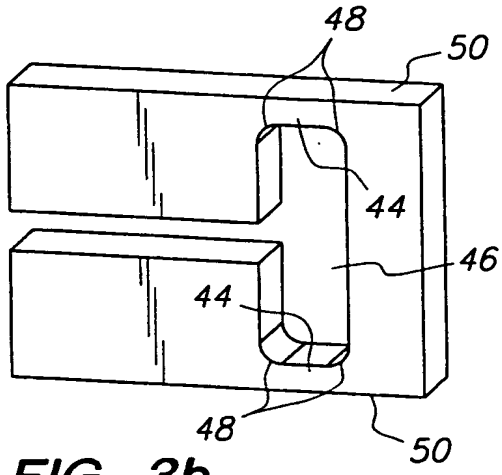

FIG. 3b

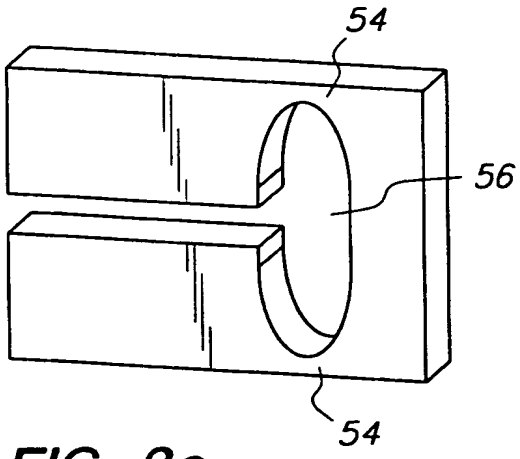

FIG. 3c

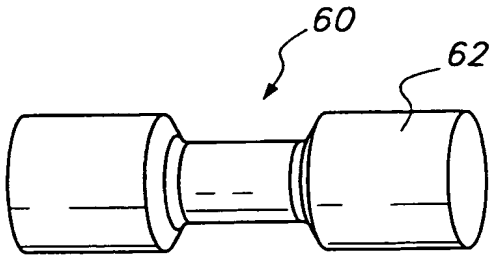

FIG. 3d

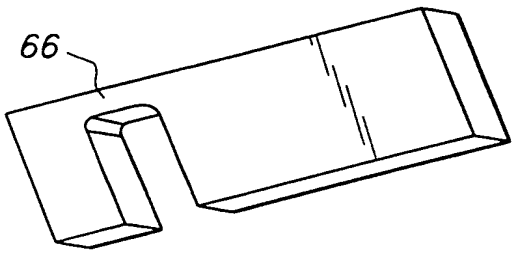

FIG. 5a

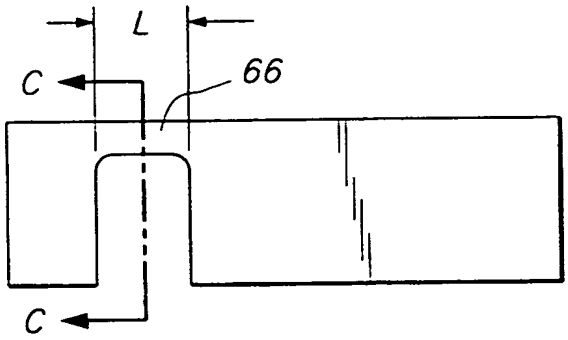

FIG. 5b

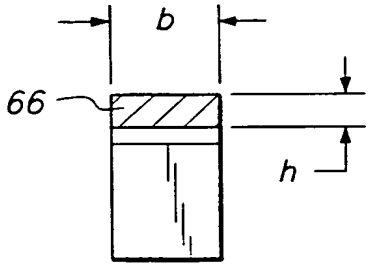

FIG. 5c

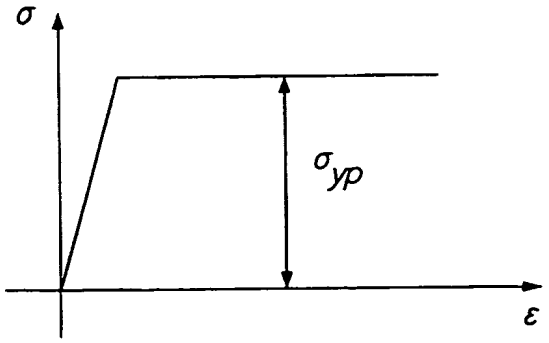

FIG. 5d

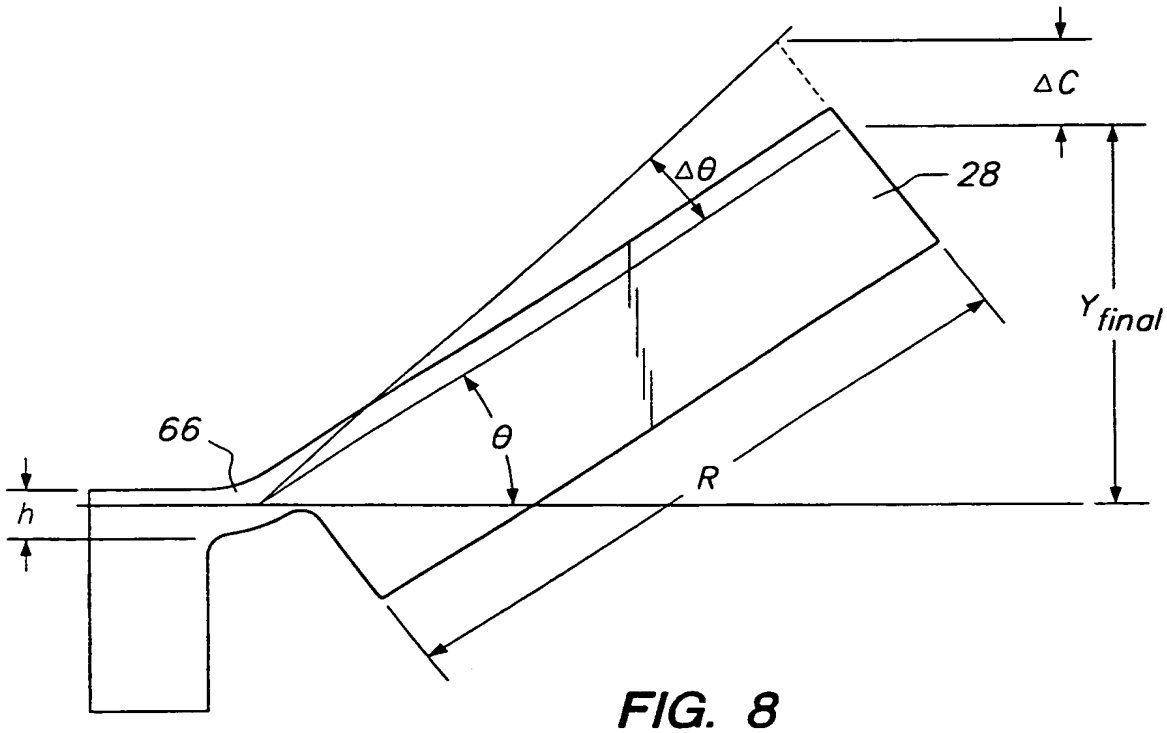

FIG. 8

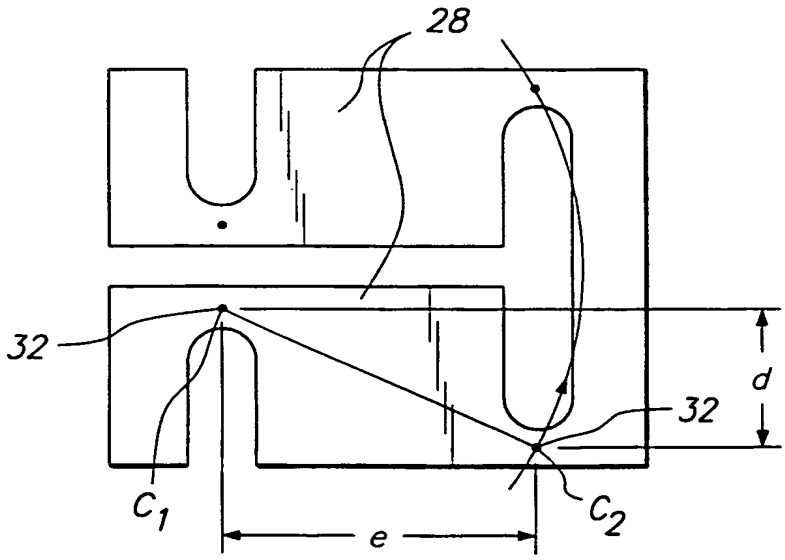

FIG. 9a

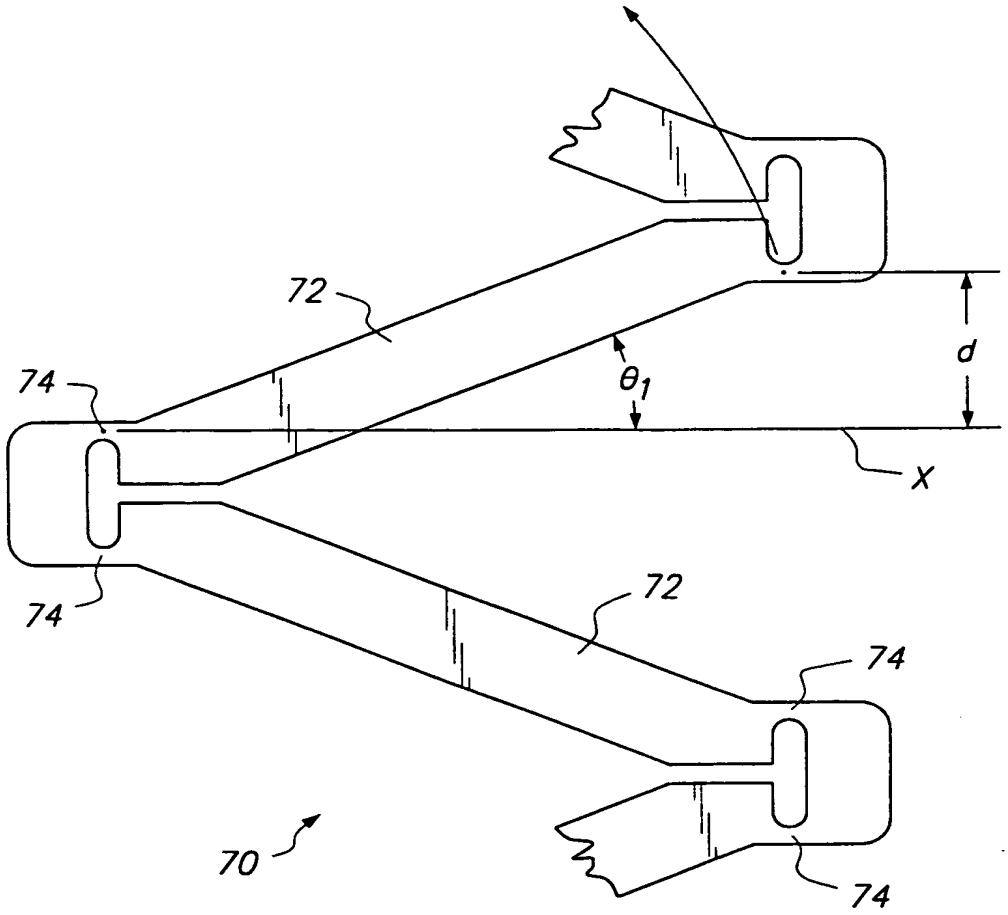

FIG. 10

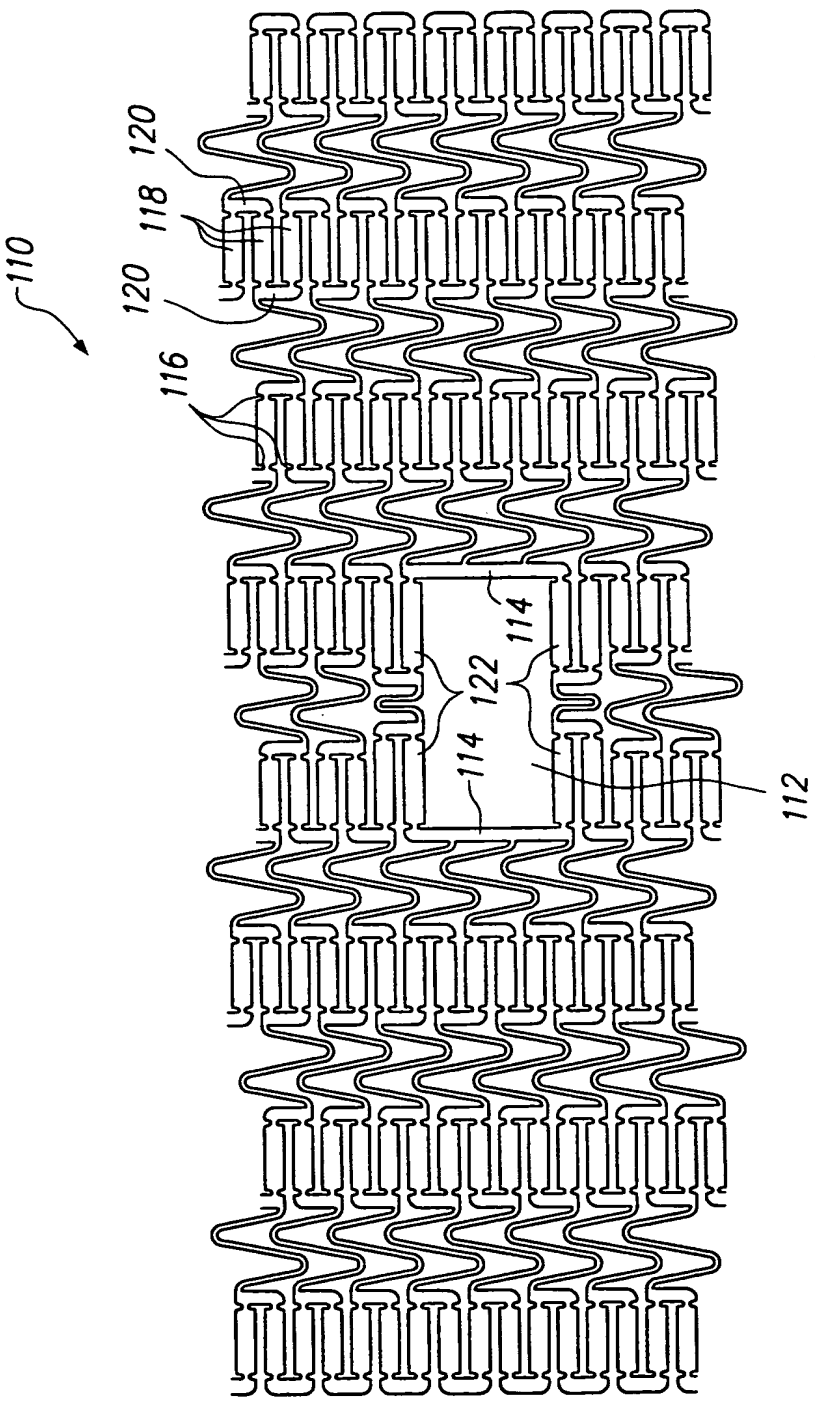

FIG. 12A

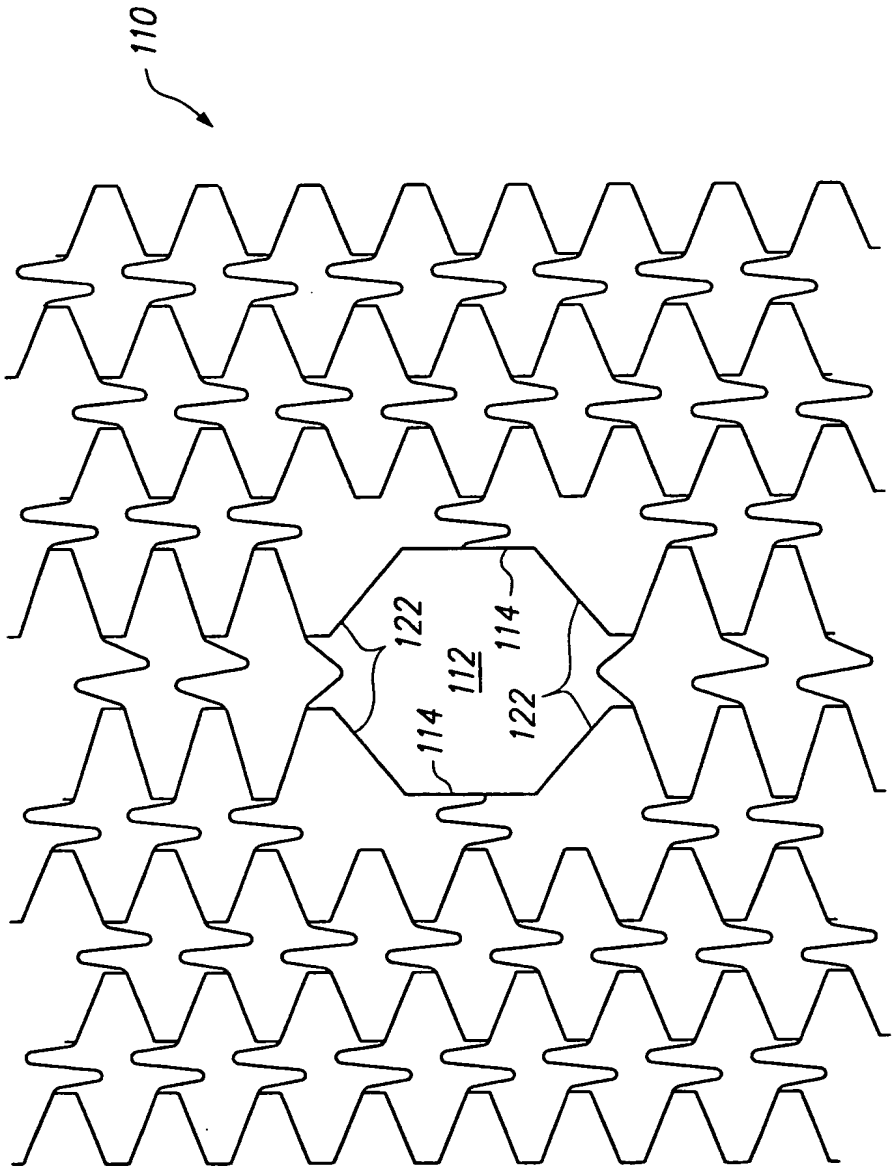

FIG. 12C

INTERNATIONAL SEARCH REPORT

information on patent family members

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